REMARKS

1. Telephone interview

The undersigned thanks the Examiner for participating in a telephone interview on January 9, 2007 to discuss distinctions between the claims of this case and the Erlanger reference discussed below. No agreement was reached.

2. Status of claims

After entry of the above amendment, claims 1-19 are pending. Claim 20 was previously canceled.

3. Support for amendment

Regarding new or amended claims, MPEP 2163 states, "While there is no *in haec verba* [in the same words] requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." From this passage, it is clear that a newly added claim limitation may be properly entered even if it is not found in the specification *verbatim*.

In part, the above amendment of claims 1 and 10 finds support in the specification at p. 8, lines 14-16. In part, the above amendment of claims 1 and 10 also finds support in the specification at p. 1, title ("Fullerenes in Targeted Therapies"); p. 2, lines 6-10 (which imply antibodies perform a targeting function in performing a therapy); p. 2, lines 12-15 (which define targeted therapies as involving drug delivery to particular sites *in vivo*); p. 2, lines 17-18 (which point to antibodies known to engage in highly specific physical interactions with particular

antigens); p. 2, lines 19-23 (which indicates that linking of antibodies and therapeutic molecules can encounter the difficulty of reaction at unintended sites which can impair the function of the antibody or the therapeutic molecule, with it being clear from context that impaired antibody function would involve a reduced ability of the antibody to perform a targeting function); p. 7, lines 14-16 (which teach that fullerenes allow for precise localization of substituent molecules); p. 8, line 14 to p. 10, line 4 (which recite a large number of medical conditions, none of which would be expected to be treated by administration of an antibody recognizing a fullerene, and a large number of specific antibodies, none of which are taught as recognizing a fullerene); p. 10, lines 5-18 and Figures 1-2 (which discuss antitumor antibodies 20, 50, linked to fullerenes); p. 10, line 24 (which teaches a C_n can be a therapeutic molecule, with the meaning of "therapeutic molecule" discussed in previously cited passages); p. 11, line 13 to p. 14, line 21 (which discuss therapeutic molecules other than C_n which can be associated to the C_n and used to treat specific diseases when delivered to a specific tissue or cell type, indicating targeting to that tissue or cell type by the antibody); and Example 3, p. 27, lines 13-26, and Figures 5-8 (which show the disulfide linkage of a substituted fullerene 100 to an antibody 110, wherein it is clear to the skilled artisan that the antibody does not recognize the fullerene and its antigen-binding site is free to recognize whatever epitope it is specific for). From these passages, it is clear to the skilled artisan that the specification implicitly disclosed a C_n-Ab structure as defined by the present claims wherein the antigen-binding site of the Ab recognizes an antigen related to a medical condition and does not recognize the C_n. This would allow targeting of the C_n (and any other therapeutic molecule linked to it) to by way of the Ab linkage. Therefore, the amendment may properly be entered.

4. Claim rejections under 35 U.S.C. §102

The Examiner rejected claims 1-3 and 7-8 under 35 U.S.C. §102(b) as being anticipated by Erlanger *et al.*, US 6,593,137 ("Erlanger"). Applicants traverse this rejection.

Erlanger discloses antibodies specific for a fullerene or a derivative thereof (col. 2, line 15-18). Erlanger teaches that a covalent linkage between a fullerene and an antibody specific thereto can be tested by (i) incubating the antibody with a fullerene derivative, in which the two materials have a paratope-epitope relationship, (ii) adding the antibody-fullerene derivative mixture to a fullerene-RSA mixture, and (iii) assaying antibody-fullerene-RSA via ELISA (col. 20, lines 4-16). A covalent linkage occurring across the paratope-epitope interface in step (i) would result in a lower amount of antibody-fullerene-RSA detected in step (iii). Erlanger also teaches that fullerene-specific rabbit antibodies generated by injection of a rabbit with a fullerene-bovine serum albumin conjugate were detected by testing rabbit serum against a fullerene-rabbit serum albumin conjugate, wherein "any [antibody] reaction will be directed at the fullerene-C60 moiety" (col. 24, lines 52-67). In summary, Erlanger teaches compositions containing antibodies and fullerenes, wherein the antigen-binding site of the antibody recognizes (is specific for) the fullerene.

The present claims, in contrast, are directed to compositions containing antigen-binding moieties and fullerenes or carbon nanotubes, wherein the antigen-binding site of the moiety does not recognize the fullerene or carbon nanotube. Therefore, Erlanger does not disclose every element of the present claims and cannot anticipate them. Applicants request this rejection of claims 1-3 and 7-8 be withdrawn.

5. Claim rejections under 35 U.S.C. §103

The Examiner rejected claims 1-19 under 35 U.S.C. §103(a) as being unpatentable over Erlanger in view of Williams *et al.*, *Int. J. Radiat. Oncol. Biol. Phys.* 1990 Sep; 19(3)633-642 ("Williams") and Østensen *et al.*, US 6,375,931 ("Østensen"). Applicants traverse this rejection.

Erlanger, discussed above, teaches antibodies specific against fullerenes. Williams discloses radiolabeled antibodies specific against tumor antigens and methods of using the radiolabeled antibodies to treat tumors. Østensen discloses compositions containing gases, therapeutic drugs, and fullerenes (col. 5, lines 66-67) and methods of targeting them to specific areas by injection (col. 7, lines 3-15) or by disrupting the fullerenes ("encapsulating or matrix material") to release the therapeutic drugs (col. 17, lines 6-23).

First, no motivation exists to add a fullerene linked to an antibody to any of the references. Williams teaches "striking tumor progression and prolonged survival" in a mouse model treated according to the method disclosed therein. Such a statement suggests to the skilled artisan that the addition of fullerenes to the compositions of Williams would be unnecessary, given the efficacy of the radiolabeled antibodies themselves. Østensen teaches fullerenes as carriers for therapeutic drugs which are encapsulated therein and released by stretching or fracture of the fullerene. The therapeutic drug can be linked to a "site-specific vector" (Østensen, col. 17, lines 6-8) for targeting to a site; such a statement suggests to the skilled artisan that the drug and the site-specific vector can be linked directly, and that use of an intermediate molecule, such as, hypothetically, a fullerene, would be unnecessary, given the apparent sufficiency of the therapeutic drug linked to the site-specific vector itself.

Second, assuming strictly for the sake of argument in this paragraph that the references could be combined, no combination of the references teaches or suggests a C_n-Ab, wherein Ab is

a moiety comprising an antigen-binding site and is linked to the C_n, wherein the antigen-binding site recognizes an antigen associated with the disease and does not recognize the C_n. The only moieties comprising antigen-binding sites taught by the references are the anti-fullerene antibodies of Erlanger and the anti-tumor antibodies of Williams. None of the references disclose a linkage between a moiety comprising an antigen-binding site that does not recognize a C_n. None suggest that such a linkage would be desirable, because the references teach efficacious treatments with compositions lacking such linkages.

For at least the foregoing reasons, Applicants submit claims 1-19 are patentable over Erlanger in view of Williams and Østensen, and request this rejection be withdrawn.

6. Conclusion

Applicants submit all pending claims are in condition for allowance. The Examiner is invited to contact the undersigned patent agent at (713) 934-4065 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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